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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorrie M. Happ	50623.132	4580

7590 06/18/2007

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/966,036	HAPP, DORRIE M.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,7,10,14-17,19,21,23,27-29,32,34,37,39-47,50 and 52-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,7,10,14-17,19,21,23,27-29,32,34,37,39-47,50 and 52-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment ands remarks filed 03/08/2007. Claims 3, 5, 8, 9, 25, 26, 33, 49 and 51 are canceled. Claims 2, 4, 7, 10, 14, 34, 39-41, 44, 47 and 52, are amended. New claims 53-64 are added. Claims 2, 4, 7, 10, 14-17, 19, 21, 23, 27-29, 32, 34, 37, 39-47, 50 and 52-64 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/08/2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 2, 7, 10, 14, 34, 39-41, 44, 50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanikanti et al. (US 5,900,425) in view of Sinclair et al. (US 5,760,118).

Kanikanti teaches solid dosage composition comprising light sensitive active agents and a light protective coating (column 4, lines 7-14). The light sensitive active agent or drug is prepared with a polymer to obtain controlled release of the active agent or drug (column 2, lines 23-35, 52-67; column 3, lines 26-46), and this meets the limitation of the first layer in the generic claims. Kanikanti states that for "light sensitive active compounds, such as nifedipine and nimodipine, the controlled release tablets must then be provided with light protective coating in order that the active compound is not degraded by light." In Kanikanti, the coating is done with HPMC film forming polymer, PEG plasticizer and titanium oxide and iron oxide light scattering and absorbing pigments (column 4, lines 6-14). The disclosure of the protective coating meets the limitation of the second layer containing protective compounds in the generic claims.

The light sensitive drug as recited in claims reads on the light sensitive drug, nifedipine and nimodipine disclosed by Kanikanti. The protective coating layer of Kanikanti does not have a drug or active agent and Kanikanti thus meets the limitation of claim 25. In the absence of factual evidence, the ratio between the drug, the compound, and the drug recited in claims 26 and 33 is not inventive over the prior art composition.

While Kanikanti discloses using titanium dioxide and iron oxide as protective compounds, Kanikanti does not disclose the use of carbon black or titanium-nitride-oxide. However, Sinclair teaches that carbon black, zinc oxide and substituted benzophenones are UV-light absorbers which when added to a composition make the composition more resistant to degradation by ultraviolet radiation (column 31, line 67 to column 32 line 4).

Regarding the ratio of the light or UV protecting compound, it is noted that there is no demonstration in applicant's specification showing that certain amount of the light or UV-protective compound relative to certain amount of the polymer in the top-coating composition (recited ratios) provides unusual results to the coated medical device. For example, the specification at paragraph [0053] of the published application, states "the ratio, by mass, of the light- and/or UV-radiation protective compound to the polymer is between about 3 to 1 (at the lower range of concentrations of the solution to be sprayed) and about 1 to 3 (at the higher range)" without further description of what if any unexpected/unusual results from the cited ratio provides to the device.

The independent claims 2, 7, 10, 14, 34, 39-41, 44, 50 and 52 reciting medical device in the preamble read on any device that can be used medically including tablet or other in vitro reagents/product/composition comprising a core and a coating layer. The first layer as recited in the claims read of a core containing an active agent and a polymer. The second layer of the claims read on a coating layer comprising a polymer. The combined references teach layered composition/product having titanium dioxide or iron oxide or carbon black as protective compounds. The difference is in the ratio between the drug and the protective compounds. Nifedipine and nimodipine of Kanikanti meets the limitation of light sensitive drug.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the light protective compound of Kanikanti or that of Sinclair in the composition of Kanikanti with the expectation that in either case, the light protective coating would protect the light sensitive drugs/active agents of Kanikanti from being degraded by that UV-light.

4. Claims 15-17, 19, 21, 23, 27-29, 42, 43 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanikanti et al. (US 5,900,425) in view of Sinclair et al. (US 5,760,118).

Kanikanti and Sinclair are discussed above. Medical device reads on any device that can be used medically including tablet or other in vitro reagents/product/composition. Kanikanti's process is a process of coating a tablet with light protective layer broadly meets the requirement for coating a medical device. As described above, Kanikanti teaches a first layer and a second layer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the light protective compound of Kanikanti or that of Sinclair in the composition of Kanikanti to coat a medical device with the expectation that in either case, the light protective coating would protect the light sensitive drugs/active agents of Kanikanti from being degraded by that UV-light.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faour (US 6,352,721) in view of Verhoff et al. (US 6,634,576).

Faour discloses a device comprising a core containing at least one expandable polymer and optionally an osmagent, a layer surrounding the core containing at least one active agent and optionally an osmopolymer, which meets the requirement for a first layer, and a membrane surrounding the layer containing the active agent and containing polymer and plasticizer which meets the requirements for a protective layer (column 3, lines 53-67). Faour contemplates formulating a variety of active agents with the device and antineoplastics are named as one of the classes of medicaments that the device can be employed to deliver (column 13, line 28) and actinomycin D and vincristine (column 14, lines 11 and 12) are specifically named.

While these drugs are light sensitive, Faour does not include light protective materials with these active agents. However, Verhoff describes formulations containing antineoplastic drugs such as vincristine and carbon black (column 55, line2; column 64, line 16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate carbon black as a diagnostic imaging agent as taught by Verhoff with the expectation of monitoring the release of the agent.

6. Claims 2, 7, 10, 14, 34, 39-41, 44, 50, 52 and 53-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanikanti et al. (US 5,900,425) in view of Sinclair et al. (US 5,760,118) and further in view of Yan (US 6,240,616).

Kanikanti and Sinclair are discussed above as rendering claims 2, 7, 10, 14, 34, 39-41, 44, 50 and 52 obvious. The combined prior art discloses the delivery of drugs such as nifedipine or nimodipine or notrendipine or nisodipine or felodipine or nicardipine. The device of the combined prior art is not a stent as is recited in claims 53-64. However, it is known in the art that several drugs such as nifedipine (column 4, lines 38, 39 and 56) are delivered to target site by means of stent that is coated with therapeutic agent (column 5, lines 38-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to deliver the combined composition of Kanikanti and Sinclair with a stent with the expectation of delivering the active agent to the target site.

7. Claims 15-17, 19, 21, 23, 27-29, 32, 37, 42, 43 and 45-47 rejected under 35 U.S.C. 103(a) as being unpatentable over Kanikanti et al. (US 5,900,425) in view of Sinclair et al. (US 5,760,118) and further in view of Yan (US 6,240,616).

Kanikanti and Sinclair are discussed above as rendering claims 15-17, 19, 21, 23, 27-29, 42, 43 and 45-47 obvious. The combined prior art discloses the delivery of drugs such as nifedipine or nimodipine or notrendipine or nisodipine or felodipine or nicardipine. The device of the combined prior art is not a stent as is recited in claims 32 and 37. However, it is known in the art that several drugs such as nifedipine (column 4, lines 38, 39 and 56) are delivered to target site by means of stent that is coated with therapeutic agent (column 5, lines 38-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a stent with the composition of Kanikanti and Sinclair in order to deliver the combined composition of Kanikanti and Sinclair to the target site.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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